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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,728	09/22/2003	Timothy R. Beevers	BE1.001	9689
23893	7590	05/16/2007	EXAMINER	
TIMOTHY E SIEGEL 1868 KNAPPS ALLEY SUITE 206 WEST LINN, OR 97068			ALI, SHUMAYA B	
		ART UNIT	PAPER NUMBER	
		3771		
		MAIL DATE	DELIVERY MODE	
		05/16/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/667,728	BEEVERS, TIMOTHY R.	

<b>Examiner</b>	<b>Art Unit</b>	
Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 September 2003.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 1-4 is/are allowed.  
 6) Claim(s) 5-16 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/18/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Objection*

**Claims 14-16 are objected to because of the following informalities:**

**In regards to claims 14-16,** claims 14-16 are considered improper method claims

because claim language does not properly claim steps to carry out a method of doing business as claimed.

**In regards to claim 14,** the language of “method of doing business” in line 1 is not supported by the specification. Consider deleting “of doing business” or replace “of doing business” with other language that are inconsistent with the language of specification.

Furthermore, in lines 2 and 3, claim recites “a plurality of differing sizes”, what size is being referred to is questionable. For the purposes of examination the term “differing sizes” is considered differing size of an individual’s nasal cannula.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 5,9,10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by**

**Kessler et al. US 6,328,038 B1**

**As to claim 5,** Kessler discloses a nasal CPAP cannula seal, comprising: (a) a strip (fig.1A, 10) of flexible material (see “a nasal cannula retainer has a flexible member” in

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**col.1, lines 21 and 22), defining a nose-covering region (fig.2, 24) that includes two nostril apertures (aperture though 34 in figures 1A, 2); (b) said strip of flexible material also defining adherence wings (fig.2, 26), adapted to adhere to a patient's cheeks (as best depicted in figure 2); (c) said strip of flexible material further defining a pair of inwardly extending cuts (parallel edges of 24 defining an open space for nose in figure 2) between said nose-covering region and said pair of wings that facilitate the folding of nose-covering region relative to said pair of wings (see fig.2).**

**As to claim 9, Kessler discloses a nasal CPAP cannula seal assembly, a nasal CPAP cannula seal, including: (i) a strip of flexible material defining a nose-covering region that includes two nostril apertures; and (ii) said strip of flexible material also defining a pair of wings, adapted to adhere to an infant's cheeks as applied to claim 5. Kessler further discloses a release liner assembly (fig.1B, 28), adhered to said nasal CPAP cannula seal and having a free portion (fig.1B, 29) that is accessible for a user to grasp in removing said release liner assembly from said cannula seal.**

**As to claim 10, Kessler discloses the nasal CPAP cannula seal assembly of claim 9 wherein said release liner includes a release liner that extends outwardly (fig.1B depicts portion 29 extending outwardly) from said cannula seal thereby forming said free portion.**

**As to claim 12, Kessler discloses the nasal CPAP cannula seal assembly of claim 9, wherein said release liner assembly comprises a release liner (fig.1B, 28) and a tab (fig.1B, 29) that is attached to said release liner and extends outwardly from said cannula seal, thereby forming said free portion.**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 6-8,11, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. US 6,328,038 B1**

**As to claim 6, Kessler discloses a nasal CPAP cannula seal, comprising:**

**(a) a strip (fig.1A, 10) of flexible material (see “a nasal cannula retainer has a flexible member” in col.1, lines 21 and 22) defining a nose-covering region (fig.2, 24) that includes two nostril apertures (aperture though 34 in figure 1A, 2); (b) said strip of flexible material also defining a pair of wings (fig.2, 26), adapted to adhere to an infant's cheeks (as best depicted in figure 2); Kessler however is silent on (c) said strip of flexible material being at least semi-transparent. However, Kessler teaches that the strip may be made out of materials commonly used for medical devices where skin contact, conformability and flexibility are required. Kessler further cites that several non-limiting examples of such material include**

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**plastic, cloth or fabric or other material (see col.3, lines 6-12 of Kessler).** Since Kessler teaches plastic material and plastic within the scope of Kessler's teaching can vary in transparency, it would have been obvious to one of ordinary skill in the art to consider Kessler's plastic to be semi-transparent or transparent.

**As to claim 7,** Kessler teaches the nasal CPAP cannula seal of claim 6 wherein said strip of flexible material is transparent (see reasoning provided for claim 6).

**As to claim 8,** Kessler discloses a nasal CPAP cannula seal assembly, comprising: (a) a nasal CPAP cannula seal including: (i) a strip (fig.1A, 10) of flexible material (see "a nasal cannula retainer has a flexible member" in col.1, lines 21 and 22) defining a nose-covering region (fig.2, 24) that includes two nostril apertures (aperture though 34 in figure 1A, 2); and (ii) said strip of flexible material also defining a pair of wings (fig.2, 26), adapted to adhere to an infant's cheeks (as best depicted in figure 2); (b) a release liner assembly (fig.1B, 28), adhered to said nasal CPAP cannula seal, for easy handling. Kessler however is silent on a sanitary package containing said nasal CPAP cannula seal adhered to said liner. However, it is obvious to one of ordinary skill in the art that medical device are commonly packaged, therefore, Kessler's seal is considered contained in a package before use.

**As to claim 11,** Kessler lacks the nasal CPAP cannula seal assembly of claim 9, wherein said release liner assembly comprises a first release liner and a second release liner that overlaps said first release liner, thereby forming said free portion. However, Applicant has not stated why the overlap is critical to the invention in terms of providing a specific function and/or solving a stated problem. Thus to one of ordinary skill in the art the release liner taught by Kessler would be consider an equivalent liner in the art because whether the liner overlaps

**or not does not really affect how the liner functions in the claimed invention. Therefore, it would have been an obvious matter of design choice to modify Kessler to derive the invention as specified in claim 11.**

**As to claim 13, Kessler lacks the nasal CPAP cannula seal assembly of claim 9, wherein said release liner assembly comprises a first release liner and a second release liner and said first release liner extends outwardly from said cannula seal as the cannula assembly is bent and bowed outwardly, thereby causing said first release liner to partially separate from said cannula seal. Difference between Kessler and the claimed invention is that Kessler lacks two separate release liner. However, at the time of the invention, medical securing device was known to have two separate release liners. Applicant's attention is requested to the invention of Thompson US 4,706,662, where two separate release liners are disclosed. Furthermore, Applicant has not stated why two liners are critical to the invention in terms of providing a specific function and/or solving a stated problem. Therefore, it would have been obvious to one of ordinary skill in the art to consider claimed liners as an obvious matter of design choice because the number of release liners would not really affect how the nasal seal functions. Therefore, it would have been an obvious matter of design choice to modify Kessler to obtain the invention as specified in claim 13.**

**As to claims 14-16, Kessler lacks a method of doing business, comprising selling nasal CPAP seals in a plurality of differing sizes cannula. However, Kessler teaches structures that would allow sealing nasal CPAP seal in a plurality of differing sizes cannula (see rejection cited for claims 5-13). Furthermore, Kessler teaches a use of nasal seal. Although its not explicitly mentioned in Kessler's disclosure, it would have been obvious to consider Kessler's device to be**

sold to a medical practitioner in order to use the device. Therefore, Kessler device further considered capable of performing method of doing business as specified in the claimed invention.

*Allowable Subject Matter*

Claims 1-4 are allowed because the prior art of record does not teach nor render obvious the overall claimed combination of a nasal CPAP cannula seal comprising a strip that further defines a set of cuts extending outwardly from each said nostril aperture.

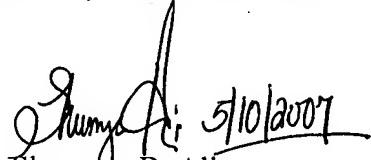
*Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Doan (US 3,460,300), Beisang, III (US 4,823,789), Dillon et al. (US 5,735,272), and Tsuug et al (US 6,966,318 B1) are cited to teach nasal cannula holder.

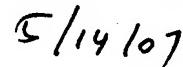
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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Art Unit 3771

  
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5/14/07